

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			<i>Complete if Known</i>		
			Application Number	10/541,195	
			Filing Date	June 30, 2005	
			First Named Inventor	Patricia SALVATI	
			Group Art Unit	1617	
			Examiner Name	Sahar JAVANMARD	
			Confirmation No.	7746	
Sheet	1	of	7	Attorney Docket No.	373987-004US (396982)

U.S. PUBLISHED DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Publication Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	A1	US-3,549,690		Leigh et al.	12-22 -1970
	A2	US-3,576,864		Nagarajan	04-27-1971
	A3	US-3,658,967		Leigh et al.	04-25-1972
	A4	US-4,049,663		Harper et al.	09-20-1977
	A5	US-4,267,354		Krapcho et al.	05-12-1981
	A6	US-4,311,853		Cree et al.	01-19-1982
	A7	US-4,513,009		Roques et al.	04-23-1985
	A8	US-4,631,287		Chakraborty et al.	12-23-1986
	A9	US-4,639,468		Roncucci et al.	01-27-1987
	A10	US-4,725,608		Nakaguchi et al.	02-16-1988
	A11	US-4,725,619		Chakraborty et al.	02-16-1988
	A12	US-4,839,369		Youssefeyeh et al.	06-13-1989
	A13	US-4,927,835		Kise et al.	05-22-1990
	A14	US-4,927,836		Holloway et al.	05-22-1990
	A15	US-5,236,957		Dostert et al.	08-17-1993
	A16	US-5,391,577		Dostert et al.	02-21-1995
	A17	US-5,446,066		Varasi et al.	08-29 -1995
	A18	US-5,449,692		Varasi et al.	09-12-1995
	A19	US-5,475,007		Cai et al.	12-12-1995
	A20	US-5,482,964		Hays	01-09-1996
	A21	US-5,498,610		Chenard	03-12-1996
	A22	US-5,502,079		Dostert et al.	03-16-1996

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	A23	US-5,670,546		Park et al.	09-23-1997
	A24	US-5,688,830		Berger et al.	11-18-1997
	A25	US-5,723,489		Sher et al.	03-03-1998
	A26	US-5,741,818		Dimmock	04-21-1998
	A27	US-5,849,737		Chaplan et al.	12-15-1998
	A28	US-5,945,454		Peverello et al.	08-31-1999
	A29	US-6,281,211		Cai et al.	08-28-2001
	A30	US-6,303,819		Peverello et al.	10-16-2001
	A31	US-6,479,484		Lan et al.	11-12-2002
	A32	US-6,500,825		Lan et al.	12-31-2002
	A33	US-7,091,210		Lan et al.	08-15-2006
	A34	US-RE40,259		Pevarello et al.	04-22-2008
	A35	US-2004/0248978		Salvati	12-09-2004
	A36	US-2007/0093495		Ruggiero et al.	04-26-2007
	A37	US-2007/0203182		Besana et al.	08-30-2007
	A38	US-2008/096965		Barbanhti et al.	04-28-2008

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Date of Publication of Cited Document MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Translation ²	
		Office	Number	Kind Code (if known)			Yes	No
	B1	EP	0200101	A2	12-10-1996	USV Pharmaceutical Corp.		
	B2	EP	0415143	A1	03-06-1991	Warner-Lambert Co.		
	B3	EP	0 525 360	A2	02-03-1993	Korea Research Institute of Chemical Technology		
	B4	GB	1140748		01-22-1969	Imperial Chemical Industries, Ltd		

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B5	GB	2059963	A	04-29-1981	A.H. Robins Co., Inc.		
B6	WO	90/14334		11-29-1990	Farmitalia Carlo Erba S.R.L.		
B7	WO	94/22808		10-13-1994	Pharmacia/Farmitalia Carlo Erba SRL		
B8	WO	94/22809		10-13-1994	Pharmacia/Farmitalia Carlo Erba		
B9	WO	96/40628		12-19-1996	The University of Saskatchewan		
B10	WO	97/05102		02-13-1997	Pharmacia & Upjohn S.p.A.		
B11	WO	97/05111		02-13-1997	Pharmacia & Upjohn S.p.A.		
B12	WO	98/19998		05-14-1998	Novartis AG		
B13	WO	98/25594		06-19-1998	SmithKline Beecham PLC		
B14	WO	98/43964		10-08-1998	Pharmacia & Upjohn S.p.A.		
B15	WO	98/47869		10-29-1998	CoCensys, Inc.		
B16	WO	99/26614		06-03-1999	CoCensys, Inc.		
B17	WO	99/35123		07-15-1999	Newron Pharmaceuticals SpA		
B18	WO	99/35125		07-15-1999	Newron Pharmaceuticals SpA		
B19	WO	99/39712		08-12-1999	CoCensys, Inc.		
B20	WO	00/61188		10-19-2000	CoCensys, Inc.		

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ²	
			Yes	No
C1	Anonymous, "Cambridge Neuroscience's grant for channel blockers," <i>SCRIP World Pharmaceutical News</i> 1870:8 (1993)			
C2	Anonymous, "Neurogen Licenses National Institutes of Health (NIH) anticonvulsants," <i>SCRIP World Pharmaceutical News</i> 1773:14 (1992)			
C3	A WOUTERS (ed.), <i>Proceedings, XIVth International Symposium on Medicinal Chemistry</i> , Maastricht, The Netherlands, 8 - 12 September 1996, Elsevier Science B.V. (Amsterdam), (cover, front matter, table of contents, index of authors, subject index, Stanford University Libraries date stamp). Copyright 1997; date stamped 24 August 1998, Swain Library, Stanford University.			
C4	Bensimon, G., et al., "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," <i>New Engl. J. Med.</i> 330:585-591 (1994)			

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C5	Brown, C.M., <i>et al.</i> , "Neuroprotective properties of Lofarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," <i>British J. Pharmacol.</i> 115:1425-1432 (1995)	
C6	Catterall, W.A., "Common modes of drug action on Na ⁺ channels: Local anesthetics, antiarrhythmics and anticonvulsants," <i>Trends Pharmacol. Sci.</i> 8:57-65 (1987)	
C7	Catterall, W.A., "Neurotoxins that Act on Voltage-Sensitive Sodium Channels in Excitable Membranes," <i>Ann. Rev. Pharmacol. Toxicol.</i> 20:15-43 (1980)	
C8	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," <i>Science</i> 242:50-61 (1988)	
C9	Complaint, Civil Action No. 1:07-cv-00487 (March 12, 2007)	
C10	Denicoff, K.D., <i>et al.</i> , "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," <i>J. Clin. Psychiatry</i> 55:70-76 (1994)	
C11	Decision, Preliminary Motions, Bd.R. 125, interference no. 105,394 (2007)	
C12	Dimmock, J.R., <i>et al.</i> , "(Aryloxy)aryl Semicarbazones and Related Compounds: A Novel Class of Anticonvulsant Agents Possessing High Activity in the Maximal Electroschock Screen," <i>J. Med. Chem.</i> 39:3984-3997 (1996)	
C13	Dostert <i>et al.</i> , "New anticonvulsants with selective MAO-B inhibitory activity," <i>European Neuropsychopharmacology</i> , 1(3):317-319 (September 1991)	
C14	ELRIFI <i>et al.</i> , "Request for <i>ex parte</i> reexamination of U.S. patent no. 6,479,484 B1," filed July 2, 2003 on behalf of Newron Pharmaceuticals, SpA	
C15	FARIELLO <i>et al.</i> , "Preclinical evaluation of PNU-151774E as a novel anticonvulsant," <i>J. Pharmacol. Exp. Ther.</i> 285(2):397-403 (May 1998)	
C16	Faravelli L. <i>et al.</i> , "NW 1029 is a novel na ⁺ channel blocker, with analgesic activity in animal models." Abstract, Annual Meeting, Society for Neuroscience 2000; 26 (1):1218	
C17	Fields, "Peripheral neuropathic pain: an approach to management," <i>in</i> PD Wall and R Melack (eds.), <i>Textbook of Pain</i> , 3 rd ed., Churchill Livingstone, pp. 991-996 (1994)	
C18	(First) Declaration of Robert A. McArthur, Pevarello Exhibit 2036, interference 105,394 (2006)	
C19	First Declaration of Stephen G. Waxman, M.D., Ph.D., PX 2003, interference no. 105,394 (2006)	
C20	Galer BS, "Neuropathic pain of peripheral origin: advances in pharmacologic treatment," <i>Neurol.</i> 45:S17-S25, 1995	
C21	Guieu <i>et al.</i> , "Central analgesic effect of valproate in patients with epilepsy," <i>Seizure</i> 2:147-150 (1993)	

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C22	Graham, S.H., <i>et al.</i> , "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," <i>J. Pharmacol. Exp. Ther.</i> 269:854-859 (1994)		
C23	Hammer <i>et al.</i> , "Effect of Riluzole on acute pain and hyperalgesia in humans," <i>Brit. J. Anaesthesia</i> 82(5):718-22 (1999)		
C24	International Search Report for PCT/EP03/12889 dated Feb. 3, 2004.		
C25	Judgment, Preliminary Motions, Bd.R. 127, interference no. 105,394 (2007)		
C26	Kingery, "A critical review of controlled clinical trials for peripheral neuropathic pain and complex regional pain syndromes," <i>Pain</i> 73:123-139 (1997)		
C27	Lunardi <i>et al.</i> , "Clinical effectiveness of lamotrigine and plasma levels in essential and symptomatic trigeminal neuralgia," <i>Neurology</i> 48(6):1714-1717 (1997)		
C28	Magnus L., "Nonepileptic uses of gabapentin experience," <i>Epilepsia</i> , 1999; 40 (Suppl. 6) S66-72; discussion 873-874		
C29	Mathew, Ninan T., "Pathophysiology, epidemiology and impact of Migraine" <i>Clinical Cornerstone</i> , vol. 4, no. 3, 2001, pages 1-17		
C30	May <i>et al.</i> , "The trigeminovascular system in humans: pathophysiologic implications for primary headache syndromes of the neural influences on the cerebral circulation," <i>J. Cereb. Blood flow Metab.</i> , vol. 9, 1999, pages 115-127		
C31	McQuay <i>et al.</i> , "Anticonvulsant drugs for management of pain: a systematic review," <i>BMJ</i> 311:1047-1052 (21 October 1995)		
C32	Memorandum Opinion and Order, interference no. 105,394 (2007)		
C33	Nakamura-Craig <i>et al.</i> , "Effect of lamotrigine in the acute and chronic hyperalgesia induced by PGE ₂ and in the chronic hyperalgesia in rats with streptozotocin-induced diabetes," <i>Pain</i> 63:33-37 (1995)		
C34	Notice Of Dismissal With Prejudice, Civil Action No. 1:07-cv-00487 (July 25, 2007)		
C35	Official action, counterpart Brazilian application (to RE40,259) no. PI 9814548-7 (translation) (AUGUST 14, 2007)		
C36	Peitl B. <i>et al.</i> , "Capsaicin-insensitive sensory-efferent meningeal vasodilation evoked by electrical stimulation of trigeminal nerve fibres in the rat," <i>British Journal of Pharmacology</i> (1999) 127, 457-467.		
C37	Peavarello <i>et al.</i> , "Synthesis and Anticonvulsant Activity of a New Class of 2-[(Arylkyl)amino]alkanide Derivatives", <i>J. Med. Chem.</i> 41:579-590 (1998)		
C38	PEVARELLO <i>et al.</i> , "Stereoselectivity, sigma binding and sodium channel blocking activity of 2-amino propanamide anticonvulsants." (3 pages) (September 12, 1996).		
C39	Puig <i>et al.</i> , "Formalin-evoked activity in identified primary afferent fibers: systemic lidocaine suppresses phase-2 activity," <i>Pain</i> 64:345-355 (1995)		

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	C40	Reuter U. <i>et al.</i> , "Experimental models of migraine", <i>Functional neurology</i> (15) Suppl. 3 9-18, 2000	
	C41	SALVATI <i>et al.</i> , "Anticonvulsant profile of FCE26743A (PNU-151774), a novel 2-aminopropionamide derivative. Society for Neuroscience. Washington. Nov 15 - 21, 1996." (4 pages) (November 21, 1996, date solely for purpose of initial consideration)	
	C42	Saxena <i>et al.</i> "Pharmacology of antimigraine drugs," <i>Journal of Neurology</i> , 1991, pages S28-S35	
	C43	Shibata <i>et al.</i> , "Modified formalin test: characteristic biphasic pain response," <i>Pain</i> 38:347-352 (1989)	
	C44	Steiner <i>et al.</i> "Lamotrigine versus placebo in the prophylaxis of migraine with and without aura" <i>Cephalgia</i> , vol. 17, 1997, pages 109-112	
	C45	Sys, P.K., <i>et al.</i> , "Ionic Mechanism of Anoxic Injury in Mammalian CNS White Matter: Role of Na, Channels and Na ⁺ -Ca ²⁺ Exchanger," <i>J. Neurosci.</i> 12:430-439 (1992)	
	C46	Supplemental data, Vieth <i>et al.</i> , "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," <i>J. Med. Chem.</i> 47:224-232 (2004) (downloaded August 20, 2007 from http://pubs.acs.org) (excerpted fields)	
	C47	Tanelian <i>et al.</i> , "Neuropathic pain can be relieved by drugs that are use-dependent sodium channel blockers: lidocaine, carbamazepine, and mexiletine," <i>Anesthesiol.</i> 74(5):949-951 (1991)	
	C48	Tanelian <i>et al.</i> , "Sodium channel-blocking agents: their use in neuropathic pain conditions," <i>Pain Forum</i> 4(2):75-80 (1995)	
	C49	Taylor, C.P. and Meldrum, B.S., "Na ⁺ channels as targets for neuroprotective drugs," <i>Trends Pharmacol. Sci.</i> 16:309-316 (1995)	
	C50	Tjolsen <i>et al.</i> , "The formalin test: an evaluation of the method," <i>Pain</i> 51:5-17 (1992)	
	C51	Vaghi <i>et al.</i> , "Neuroprotective effect of PNU-151774E, a new anticonvulsant compound, in the model of global ischaemia in gerbils." (5 pages) (October 30, 1997, date solely for purpose of initial consideration)	
	C52	Varasi <i>et al.</i> , "Synthesis and anticonvulsant activity of new benzyloxybenzylacetamide derivatives," from <i>Abstracts, XIIth International Symposium on Medicinal Chemistry</i> , Basel, Switzerland, September 13-17, 1992 (2 pages) (1992)	
	C53	Varasi <i>et al.</i> , "Synthesis and anticonvulsant activity of new benzyloxybenzylacetamide derivatives" (2 pages) (1992)	
	C54	Vieth <i>et al.</i> , "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," <i>J. Med. Chem.</i> 47:224-232 (2004)	
	C55	Webber, "Observations under article 115 EPC", filed November 19, 2002 in EP 98958114.5 (EP 1032377) on behalf of Newron Pharmaceuticals, SpA	

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	C56	Wenzel <i>et al.</i> : "Migraine headache misconceptions: barriers to effective care" <i>Pharmacotherapy</i> , vol. 24, no. 5, 2004, pages 638-648		
	C57	Wilton, "Tegretol in the treatment of diabetic neuropathy," <i>S. Afr. Med. J.</i> 48(20):869-872 (1974)		
	C58	Woolf <i>et al.</i> , "The systemic administration of local anaesthetics produces a selective depression of C-afferent fibre evoked activity in the spinal cord," <i>Pain</i> 23(4):361-374 (1985)		

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